



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,365	07/19/2005	Lionel Tarassenko	117-537	5031
23117 7590 01/29/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER NAQI, SHARICK	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

AR

Office Action Summary	Application No. 10/528,365	Applicant(s) TARASSENKO ET AL.	
	Examiner Sharick Naqi	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-30 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-30 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-11, 13-16, 18-30 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Blants et al. USPN 6,231,519.

1. A telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based measurement and data transmittal device comprises:

an electronic physiological data acquisition unit for measuring a physiological parameter of a patient to acquire and output data representing the parameter; (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As an example, the Peak Expiratory Flow meter is used to provide physiological measurements to a server using a wireless network. GPS, time/date also provided.)

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server; and (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As an

example, the Peak Expiratory Flow meter is used to provide physiological measurements to a server using a wireless network accessed by the mobile data communications device)

a display for displaying to the patient the data and a message related to the patient's condition, (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As can be seen in Figure 3, the communication device has a display and column 5, lines 30-35 states that the individual receives a warning if they go to an area where the risk level is high for their particular ACT and column 4 lines 56-60 mentions feedback provided to users in the form of individual notification. It is the Examiner's position that the warning is equivalent to a message related to the person's condition.)

wherein the system is adapted to analyze the data automatically with reference to known trends for the patient and in response automatically to generate and display on said display said message related to the patient's condition . (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. The collected data from the individual user and others is analyzed by server which identifies different asthma types and connects the symptoms of each type with air quality patterns, allowing cross-correlation and cross-mapping (known trends), and feedback is provided in the form of individual notifications to users as stated in column 4, lines 42-60. Additionally, column 5, lines 30-35 states that the results or trends are available to users as private advice and the individual receives a warning if they go to an area where the risk level is high for their particular ACT (message related to the patient's condition))

Claims 2-5, 8-16 and 18-30 are rejected on substantially the same basis. See previous office action.

36. A telemedicine method comprising:

measuring a physiological parameter of a patient using a patient –based device to acquire and output data representing the parameter; (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As an example, the Peak Expiratory Flow meter is used to provide physiological measurements to a server using wireless network accessed by the mobile data communication device)

automatically wirelessly transmitting the output data via a wireless network to a remote server; (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As an example, the Peak Expiratory Flow meter is used to provide physiological measurements to a server using wireless network accessed by the mobile data communication device)

analyzing the data automatically with reference to known trends for the patient and in response automatically generating a message related to the patient's condition; and (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. The collected data from the individual user and others is analyzed by server which identifies different asthma types and connects the symptoms of each type with air quality patterns, allowing cross-correlation and cross-mapping (known trends), and feedback is provided

in the form of individual notifications to users as stated in column 4, lines 42-60.

Additionally, column 5, lines 30-35 states that the results or trends are available to users as private advice and the individual receives a warning if they go to an area where the risk level is high for their particular ACT (message related to the patient's condition))

displaying via a display of the patient-based device the message related to the patient's condition. (column 2, lines 52-65, column 4, lines 1-67, column 5, lines 1-67. As can be seen in Figure 3, the communication device has a display and column 5, lines 30-35 states that the individual receives a warning if they go to an area where the risk level is high for their particular ACT and column 4 lines 56-60 mentions feedback provided to users in the form of individual notification. It is the Examiner's position that the warning is equivalent to a message related to the person's condition)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8-11, 13, 15, 18-23, 28-30 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al. USPN 6,443,890 and Phipps USPN 6,579,231.

For claim 1, Schulze discloses a telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based measurement and data transmittal device comprises:

an electronic physiological data acquisition unit for measuring a physiological parameter of a patient to acquire and output data representing the parameter; (Fig. 2, column 2, lines 15-61. Various sensors measuring physiological data)

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server; (column 2, lines 15-61, column 3, lines 1-59. Data sent to server as stated in column 3, lines 17-19)

and

wherein the system is adapted to analyze the data automatically with reference to known trends for the patient and in response automatically to generate a message

related to the person's condition. (column 2, lines 15-61, column 3, lines 1-59, column 4, lines 55-63, column 5, lines 32-60, column 6, lines 40-43. According to column 3, lines 29-35 and column 4, lines 55-62, trends detected by analyzing the patient's archived data and caregiver's knowledge of the condition of the patient are used to set the alarms (known trends). Additionally column 5, lines 47-60 discloses logic that transmits alarm conditions as messages provided to the patient whenever alarm characteristics are fulfilled. These messages are provided by various means including a voice synthesizer that provides a voice alert (audio message) that a particular alarm has occurred. Thus Schulze meets the limitation of analyzing the data automatically with reference to known trends for the patient and in response generating a message related to the patient's condition)

Schulze discloses that the message is an audio message delivered by a voice synthesizer (column 5, lines 47-60). Schulze does not disclose a display for displaying to the patient the data and a message related to the patient's condition. However Phipps, a reference in an analogous art, discloses a portable personal monitoring device with an LCD screen and teaches that on detection of an alarm condition the system displays a message on the LCD screen including the subject's current medical condition and brief instructions to limit activities, in order to inform the patient of their medical condition (Phipps column 5, lines 20-35). Both devices teach delivering a message regarding a patient's condition to the patient. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the audio message delivery system of Schulze with the known visual message delivery system

and associated LCD display taught by Phipps for the predictable result of notifying the patient with a message regarding his medical condition.

2. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to receive automatically the output data from the physiological data acquisition unit on data acquisition thereby, and thereupon automatically to transmit the output data immediately in real time to the remote server. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

3. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to establish a connection to the wireless network automatically when it is switched on and to maintain the connection while switched on. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

4. A telemedicine system according to claim 1, wherein the wireless network is a packet-switched network. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

5. A telemedicine system according to claim 4 wherein the wireless network is a public network. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

8. A telemedicine system according to claim 1 wherein the wireless transmitter is one of a cellular telephone and a pda. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

9. A telemedicine system according to claim 8 wherein a software application is provided on the one of a cellular telephone and a pda to interface with the physiological data acquisition unit and to control data transmission to the remote server. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

10. A telemedicine system according to claim 1 wherein the patient-based measurement and data transmittal device is adapted to check the acquired data for compliance with preset conditions. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 25, lines 25-60)

11. A telemedicine system according to claim 10 wherein the preset conditions relate to the quality or completeness of the data or the condition of the patient. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

13. A telemedicine system according to claim 1 wherein the patient-based measurement and data transmittal device stores the data if a network connection is

unavailable and automatically retransmits it later when a network connection is available. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

15. A telemedicine system according to claim 1 wherein the remote server formats the data for delivery and display to a clinician. (Schulze column 3, lines 17-19, column 4 lines 34-62)

18. A telemedicine system according to claim 1 wherein the physiological data acquisition unit is one of: an electronic flow meter for recording Peak Expiratory Flowrate, an electronic blood glucose meter, a blood pressure monitor, and a heart rate monitor. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

19. A telemedicine system according to claim 1 wherein the physiological data acquisition unit and wireless transmitter are integrated as a single device. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67)

20. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter is time stamped with reference to a secure clock. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

21. A telemedicine system according to claim 20 wherein the secure clock is provided in

the patient-based physiological data acquisition and transmittal device. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

22. A telemedicine system according to claim 1 wherein a secure data store is provided in the patient-based physiological data acquisition and transmittal device. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

23. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter is digitally signed. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

28. A telemedicine system according to claim 1 wherein the electronic physiological data acquisition unit is connectable to the a wireless transmitter by a connection comprising a data head including an interface. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

29. A telemedicine system according to claim 28 wherein the data head comprises a secure clock for time stamping the data. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

30. A telemedicine system according to claim 28 wherein the data head comprises a

secure memory for storing the data. (Schulze column 2, lines 15-61, column 3, lines 1-59, column 4, lines 1-67, column 5, lines 25-60)

Claim 36 is rejected on substantially the same basis as claim 1 above.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Schulze et al. USPN 6,443,890 and Phipps USPN 6,579,231 as applied to claim 5 above, and further in view of Haller et al. US Patent Pub. No. 2002/0052539.

Schulze teaches in column 5, lines 25-32 and column 7, lines 10-29, that the CDMA wireless protocol is used in the device but other wireless networks will be just as suitable for use in the device. Schulze does not disclose that the wireless network is the General Packet Radio Service (GPRS) network. However, Haller et al., a reference in an analogous art, discloses, in paragraphs 0115-0141, the use of a GPRS network in an emergency medical information communication system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the wireless network of Schulze et al. with Haller et al.'s GPRS network since Haller et al. teaches, in paragraphs 0115-0141, the interchangeability of different wireless networks, including CDMA and GPRS.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Schulze et al. USPN 6,443,890 and Phipps USPN 6,579,231 as applied to claim 1 above, and further in view of Haller et al. US Patent Pub. No. 2002/0052539.

Schulze teaches in column 5, lines 25-32 and column 7, lines 10-29, that the CDMA wireless protocol is used in the device but other wireless networks will be just as suitable for use in the device. Schulze does not disclose that the wireless network is the 3G, PDC-P or EDGE network. However, Haller et al., a reference in an analogous art, discloses, in paragraphs 0115-0141, the use of a 3G network in an emergency medical information communication system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the wireless network of Schulze et al. with Haller et al.'s 3G network since Haller et al. teaches, in paragraphs 0115-0141, the interchangeability of different wireless networks, including CDMA and 3G.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blants et al. USPN 6,231,519 as applied to claim 16 above, and further in view of Baker, Jr. et al. USPN 5,853,364.

Blants discloses that the server receives physiological information from a sensor and analyzes the data along with data from other users to identify trends and provided the information to individual users (Blants column 2, lines 52-64, column 4, lines 35-60, column 5, lines 29-35). Blants does not disclose that the data analyzer comprises a Kalman smoother for smoothing the data. Baker, Jr. et al., a reference in an analogous art, discloses, in column 4, lines 4-25, the use of a Kalman filter to reduce noise energy in a system for measuring physiological parameters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the data analyzer of Blants et al. with Baker, Jr. et al.'s Kalman filter because Baker Jr. et al. teaches in

column 4, lines 4-25 and column 9, lines 58-60, that the Kalman filter optimally filters noise from physiological measurements and further teaches, in column 11, lines 22-36, that the Kalman filter improves accuracy of the results.

Response to Arguments

Applicant's arguments filed on November 7, 2007 have been fully considered but they are not persuasive.

Applicant argues that Blants et al. lacks automatic transmission of the data to the server. Examiner respectfully disagrees. Blants states "The data from the mobile communication tool is provided to a server 130" (column 4, lines 34-36).

Applicant additionally argues that Blants et al. lacks adaptation of the analysis to personal trends of the patient. Examiner respectfully disagrees. Lines 11-13 of claim 1 state, "... the system is **adapted to** analyze the data automatically with reference to known trends for the patient and in response automatically to generate and display on said display said message related to the patient's condition." The applicant is respectfully reminded that "**adapted to**" in the claims may properly be interpreted as "capable of", which does not require that the reference actually teach the intended use of the element, a recitation of the intended use of the claimed invention must result in a structural different between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that the prior art is capable of performing the intended use.

However, even if the intended use language was not used, the limitation is still met because Blants discloses that the collected data from the individual user and others is analyzed by the server to identify different asthma types and connect the symptoms of each type with air quality patterns, allowing cross-correlation and cross-mapping (equivalent to analysis with reference to known trends), and then feedback is provided in the form of individual notifications to users (column 4, lines 35-60). Additionally, column 5, lines 30-35 state that the results or trends are available to users as private advice and the individual receives a warning if they go to an area where the risk level is high for their particular ACT (equivalent to generating a message related to the patient's condition). This disclosure of data analysis and transmission of a warning is sufficient to meet the limitation. Thus Blants properly rejects the claim.

Applicant's arguments with respect to Schulze et al. USPN 6,443,890 are moot based on the new grounds of rejection.

Applicant is invited to request an interview to discuss suggestion to overcome the applied prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharick Naqi whose telephone number is 571-272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/528,365
Art Unit: 3736

Page 17

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharick Naqi
January 24, 2008

A handwritten signature in black ink, appearing to read "Sharick Naqi", located in the bottom right corner of the page.